

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Peter Wernet	Confirmation No.:	5815
Serial No.:	10/758,644	Art Unit:	1633
Filed:	January 15, 2004	Examiner:	Quang Nguyen
Customer No.:	21559		
Title:	HUMAN CORD BLOOD DERIVED UNRESTRICTED SOMATIC STEM CELLS (USSC)		

REQUEST FOR RECONSIDERATION AND RENEWED APPLICATION

FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth in the Issue Notification mailed in connection with the above-captioned patent application on June 17, 2009, and as set forth on the cover of U.S. Patent No. 7,556,801 B2 ("the '801 patent"), issued July 7, 2009, Applicant hereby requests reconsideration of the patent term adjustment. Applicant submits that the current patent term adjustment should be 595 days, not 570 days as shown in the Patent Term Adjustment History on the PAIR system (Exhibit I).

Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

* * *

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a)(1), (2), and (4), and in 1.703(a)(1) and (4). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States,

* * *

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, **is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004). However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added in bold; original emphasis in italics):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before*

it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

Wyeth v. Dudas, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at *3 (D.D.C. Sep. 30, 2008).

Accordingly, Applicant submits that, where A delay occurs entirely before the three-year date, and thus does not overlap the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

Patent Term Adjustment for the ‘801 Patent

Patent Office Delay

Two periods of A delay are shown in Exhibit I: The delay of 175 days associated with the mailing of the Restriction Requirement dated September 6, 2005, and the delay of 40 days associated with the delay in issuing the ‘801 patent. Thus, according to Exhibit I, the total A delay is 215 days. This result is consistent with the Office’s determination as shown in Exhibit I.

Under 37 C.F.R. §§ 1.702(b) and 1.703(b), the time interval between the date that is three years from the actual filing date of the application and the date the patent issues counts as B delay. The filing date was January 15, 2004, resulting in a three-year date of January 15, 2007. The ‘801 Patent issued on July 7, 2009, or 904 days later. Accordingly, the period of B delay is 904 days, which is consistent with the Office’s calculation, as shown in Exhibit I.

When the periods of A delay and B delay do not overlap, Applicant is entitled to both periods of delay (*see Wyeth, supra*). Here, the period of A delay under 154(b)(1)(A)(i) ran from

March 15, 2005, until September 6, 2005, and the period of A delay under 154(b)(1)(A)(iv) ran from May 28, 2009, until July 7, 2009. The period of B delay began on January 15, 2007, and ran until July 7, 2009. Thus, the period of A delay under 154(b)(1)(A)(i) and the period of B delay do not overlap, and Applicant is entitled, under U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f), to the sum of these periods in the patent term adjustment calculation, for a total Office delay of $175 + 904$ days = 1079 days rather than 904 days, as determined by the Office (see Exhibit I). Applicant notes that the 40 day Patent Office delay under 35 U.S.C. § 154(b)(1)(A)(iv) for failure to issue a patent within 4 months after the date on which the issue fee was paid should not be added to the total Patent Office delay because these calendar days overlap with calendar days used to calculate Patent Office delay under 35 U.S.C. § 154(b)(1)(B).

Applicant Delay

Based on an analysis of 37 C.F.R. § 1.704, Applicant submits that the Office's calculation of total Applicant delay should be 484 days, rather than 334 days as shown in Exhibit I.

Applicant discusses the basis for this calculation below.

The Office mailed a first non-final Office Action on October 28, 2005. Under 37 C.F.R. § 1.704(b), the period of patent term adjustment is reduced by the number of days in excess of three months after the mailing of an action by the Office that it takes for Applicant to respond. Thus, Applicant delay in this case began to accrue after January 28, 2006. Applicant filed a response to the Office Action on April 27, 2006; the Office received the response on May 2, 2006. Subsequently, on May 19, 2006, Applicant submitted an Information Disclosure Statement, which the Office received on May 22, 2006. In addition, the Office mailed a Notice of Non-Compliant Amendment on July 31, 2006, to which Applicant responded on August 15, 2006; the Office received this response on August 18, 2006. Thus, Applicant delay in response

to the first non-final Office Action runs from January 28, 2006, until August 18, 2006, which equals 202 days. The Office's calculation of delay was only 94 days.

Next, the Office mailed a second non-final Office Action on November 13, 2006. Applicant delay in response to this Office Action began to accrue after February 13, 2007. Applicant filed a response to the second non-final Office Action on May 14, 2007; the Office received the response on May 16, 2007. Subsequently, on June 25, 2007, Applicant submitted a second Information Disclosure Statement, which the Office received on June 27, 2007. Thus, Applicant delay in response to the second non-final Office Action runs from February 13, 2007, until August 27, 2007, which equals 134 days. The Office's calculation of delay was only 92 days.

The Office mailed a third non-final Office Action on November 8, 2007. Applicant delay in response to this Office Action began to accrue after February 8, 2008. Applicant filed a response to the third non-final Office Action on April 7, 2008. Subsequently, on June 13, 2008, Applicant submitted a third Information Disclosure Statement, which the Office received on June 16, 2008. Thus, Applicant delay in response to the third non-final Office Action runs from February 8, 2008, until June 16, 2008, which equals 129 days. This calculation is consistent with the Office's calculation of delay.

Finally, the Office mailed a final Office Action on July 1, 2008. Applicant delay in response to this Office Action began to accrue after October 1, 2008. Applicant filed a response to the final Office Action on October 20, 2008. Thus, Applicant delay in response to the final Office Action is 19 days, which is consistent with the Office's calculation.

Thus, total Applicant delay in the '801 patent is 202 days + 134 days + 129 days + 19 days = 484 days.

Patent Term Adjustment for the '801 Patent

For the reasons discussed above, Applicant concludes that the total Office delay associated with the '801 patent is 1079 days, while the total Applicant delay is 484 days. Thus, the '801 patent is entitled to a total of 595 days (1079 days – 484 days = 595 days) of patent term adjustment under 37 C.F.R. § 1.703. Applicant requests that the patent term adjustment determination be corrected accordingly.

The '801 Patent is not subject to a Terminal Disclaimer.

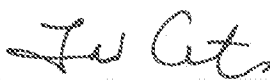
CONCLUSION

Applicant submits that the current patent term adjustment should be 595 days and hereby requests reconsideration of the patent term adjustment.

No fee is believed to be due, as payment of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e) was previously submitted with the Application for Patent Term Adjustment filed on January 28, 2009 (see also the Decision on Petition mailed on June 9, 2009, a copy of which is provided herewith). If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 4 September 2009



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Exhibit I



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10/768,644 HUMAN CORD BLOOD DERIVED UNRESTRICTED SOMATIC STEM CELLS (USSC)

Select	Applications by Attorney Docket	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Continuity Data	Fees	Published Documents	Address & Attorney/Agent	Supplements Content	Display References
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Patent Term Adjustment

Filing or 371(c) Date:	01-15-2004	USPTO Delay (PTO) Delay (days):	904
Issue Date of Patent:	07-07-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	334
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	570
USPTO Adjustment (days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
06-17-2009	PTA 36 Months	689	
07-07-2009	Patent Issue Date Used in PTA Calculation	40	
06-11-2009	Dispatch to FDC	+	
06-11-2009	Email Notification	+	
06-09-2009	Mail-Petition Decision - Dismissed	+	
06-08-2009	Petition Decision - Dismissed	+	
01-28-2009	Petition Entered	+	
01-30-2009	Application Is Considered Ready for Issue	+	
01-28-2009	Statement Filed Indicating a Loss of Entitlement to Small Entity Status	+	
01-28-2009	Issue Fee Payment Verified	+	
01-28-2009	Issue Fee Payment Received		
01-14-2009	Receipt into Pubs		
12-12-2008	Receipt into Pubs		
12-12-2008	Sequence Forwarded to Pubs on Tape		
12-03-2008	Mail Notice of Allowance		
11-26-2008	Notice of Allowance Data Verification Completed		
11-26-2008	Case Docketed to Examiner in GAU		
11-26-2008	Document Verification		
11-24-2008	Examiner's Amendment Communication		
11-18-2008	Examiner Interview Summary Record (PTOL - 413)		
06-16-2008	Information Disclosure Statement considered		
11-13-2008	Date Forwarded to Examiner		
10-20-2008	Amendment after Final Rejection		19
10-20-2008	Request for Extension of Time - Granted		+
06-16-2008	Reference capture on IDS		+
06-16-2008	Information Disclosure Statement (IDS) Filed		70
07-03-2008	Electronic Review		+
07-01-2008	Email Notification		+
07-01-2008	Mail Final Rejection (PTOL - 326)		+
06-16-2008	Information Disclosure Statement (IDS) Filed		+
06-23-2008	Final Rejection		+
04-26-2008	Date Forwarded to Examiner		+
04-07-2008	Response after Non-Final Action		59
04-07-2008	Request for Extension of Time - Granted		+
11-10-2007	Electronic Review		+
11-08-2007	Email Notification		+
11-08-2007	Mail Non-Final Rejection		+
11-05-2007	Non-Final Rejection		
10-24-2007	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
11-02-2007	Date Forwarded to Examiner		
10-24-2007	Amendment after Final Rejection		
11-01-2007	Email Notification		
11-01-2007	Mail Examiner Interview Summary (PTOL - 413)		
03-08-2007	Examiner Interview Summary Record (PTOL - 413)		
08-01-2007	Mail Final Rejection (PTOL - 326)		
07-27-2007	Final Rejection		
06-27-2007	Information Disclosure Statement considered		
06-27-2007	Information Disclosure Statement (IDS) Filed		
06-03-2007	Date Forwarded to Examiner		
05-16-2007	Response after Non-Final Action		92
05-16-2007	Request for Extension of Time - Granted		+
05-04-2007	Mail Examiner Interview Summary (PTOL - 413)		+
03-08-2007	Examiner Interview Summary Record (PTOL - 413)		+
11-13-2006	Mail Non-Final Rejection		+
11-13-2006	Non-Final Rejection		
09-09-2006	Date Forwarded to Examiner		
08-18-2006	Response after Non-Final Action		
07-31-2006	Mail Miscellaneous Communication to Applicant		
07-24-2006	Miscellaneous Action with SSP		
05-22-2006	Information Disclosure Statement considered		
05-22-2006	Information Disclosure Statement (IDS) Filed		
05-22-2006	Information Disclosure Statement (IDS) Filed		
05-02-2006	New or Additional Drawing Filed		
05-02-2006	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
05-09-2006	Date Forwarded to Examiner		

05-02-2006	Response after Non-Final Action	94
05-02-2006	Request for Extension of Time - Granted	+
10-28-2005	Mail Non-Final Rejection	+
10-27-2005	Non-Final Rejection	
10-18-2005	Date Forwarded to Examiner	
10-11-2005	Response to Election / Restriction Filed	
09-06-2005	Mail Restriction Requirement	175
09-01-2005	Requirement for Restriction / Election	+
01-15-2004	Information Disclosure Statement considered	+
06-28-2005	Case Docketed to Examiner in GAU	+
04-16-2005	IFW TSS Processing by Tech Center Complete	+
04-16-2005	Case Docketed to Examiner in GAU	+
01-15-2004	Preliminary Amendment	+
01-15-2004	Reference capture on IDS	+
01-15-2004	Information Disclosure Statement (IDS) Filed	+
01-15-2004	Information Disclosure Statement (IDS) Filed	+
03-22-2005	Application Return from OIPE	+
03-22-2005	Application Return TO OIPE	+
03-21-2005	Application Dispatched from OIPE	+
03-22-2005	Application Is Now Complete	+
03-03-2005	Additional Application Filing Fees	+
03-03-2005	Applicant has submitted new drawings to correct Corrected Papers problems	+
03-03-2005	Applicant has submitted a new specification to correct Corrected Papers problems	+
08-23-2004	Additional Application Filing Fees	+
08-23-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant	+
08-23-2004	Applicant has submitted new drawings to correct Corrected Papers problems	+
08-23-2004	Applicant has submitted a new specification to correct Corrected Papers problems	+
01-03-2005	Notice Mailed--Application Incomplete--Filing Date Assigned	+
03-04-2004	Cleared by OIPE CSR	+
02-03-2004	CRF Is Good Technically / Entered into Database	+
01-28-2004	IFW Scan & PACR Auto Security Review	+
01-15-2004	CRF Disk Has Been Received by Preexam / Group / PCT	+
01-15-2004	Initial Exam Team nn	+

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MAILED

JUN 09 2009

In re Application	:	OFFICE OF PETITIONS
Wernet	:	
Application No. 10/758,644	:	PATENT TERM ADJUSTMENT
Filed: January 15, 2004	:	
Dkt. No.: 07588/026003	:	

This is in response to the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705." This matter is being properly treated as an application for patent term adjustment pursuant to 37 CFR 1.705(b). The application for patent term adjustment was timely filed January 28, 2009, along with issue fee payment.

Applicant does not dispute the adjustment of to date of zero days (adjustment totalling 175 days for Office delays less reductions totalling 334 days for applicant delays). Instead, applicant contests the adjustment insofar as it relates to the Office's failure to issue the patent within three years of the filing date of the application pursuant to 37 CFR 1.703(b) in view of Wyeth v. Dudas, No. 07-1492 (D.D.C. September 30, 2008).

To the extent that this application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, a decision is being held in abeyance until after the actual patent date. Knowledge of the actual date the patent issues is ordinarily required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See, 37 CFR 1.703(b). It is noted that at the time of this decision, the patent has not issued.

Applicant is given **TWO (2) MONTHS** from the issue date of the patent to file a written request for reconsideration of the patent term adjustment for Office failure to issue the patent within 3 years. A copy of this decision should accompany the

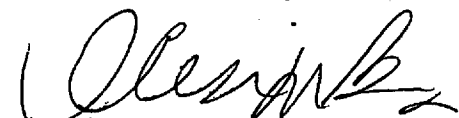
request. Applicant may seek such consideration without payment of an additional fee. However, as to all other bases for seeking reconsideration of the patent term adjustment indicated in the patent, all requirements of § 1.705(d) must be met. Requests for reconsideration on other bases must be timely filed and must include payment of the required fee.

With respect to the over 3 year calculation, rather than file the request for reconsideration of Patent Term Adjustment at the time of the mailing of the notice of allowance, applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term pursuant to 37 CFR 1.705(d). The USPTO notes that it does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent and accordingly, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The application file is being forwarded to the Office of Patent Publication for issuance of the patent. The patent term adjustment indicated on the patent (as shown on the Issue Notification mailed about three weeks prior to patent issuance) will include any additional adjustment accrued both for Office delay in issuing the patent more than four months after payment of the issue fee and satisfaction of all outstanding requirements, and for the Office taking in excess of three years to issue the patent (to the extent that the three-year period does not overlap with periods already accorded).

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.



Alesia M. Brown
Petitions Attorney
Office of Petitions